

### **REMARKS**

This paper includes a complete and timely response to the Final Office Action mailed July 26, 2004. Upon entry of the attached amendments, claims 1 - 3, 5, 6, 8 - 14, and 20 - 30 remain pending. Independent claims 1 and 20 have been amended. Claims 4, 7, and 15 - 19 have been canceled without prejudice, waiver, or disclaimer. Applicant reserves the right to pursue the subject matter of these canceled claims in a continuing application, if Applicant so chooses, and does not intend to dedicate the canceled subject matter to the public. Claims 28 - 30 have been added. The subject matter of amended claims 1 and 20, and new dependent claims 28 - 30 is at least included in FIGs. 4 - 9C and described in the corresponding portions of the detailed description. Accordingly, no new matter is added to the present application.

Applicants respectfully submit that the now pending claims 1 - 3, 5, 6, 8 - 14, and 20 - 30 are patentable over the cited art of record. Accordingly, reconsideration and allowance of the application and presently pending claims are respectfully requested.

#### **I. Office's Final Rejection is Improper**

Applicant hereby respectfully submits that the finality of the present rejection of Applicant's claim 11 is improper. Applicant reminds the Office that Applicant's originally submitted claim 11 was not specifically rejected in the Office Action mailed February 12, 2004. Consequently, the present outstanding rejection of claim 11 is made under new grounds of rejection. Thus, the present Office Action should be a non-final rejection.

Should the Office disagree and maintain the finality of the present rejection of Applicant's pending claims, Applicant's amendments to the claims should be accepted as they raise no new issues and place the pending claims in condition for allowance.

#### **II. Claim Rejections under 35 U.S.C. §103 - Claims 1 - 14, and 20 - 27**

##### **A. Statement of the Rejection**

The Office Action indicates that claims 1 - 14 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Shoor (U.S. Patent No. 4,266,106), hereafter "*Shoor*" in view of Desecki *et al.* (U.S. Patent No. 5,658,260), hereafter "*Desecki*."

The Office Action further indicates that claims 13 and 20 - 27 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over *Shoor* in view of *Desecki* further in view of *Graves et al.* (U.S. Patent No. 5,437,648), hereafter "*Graves*."

**B. Discussion of the Rejection - Claims 1 - 14**

In order for a claim to be properly rejected under 35 U.S.C. §103, the combined teachings of the prior art references must suggest all features of the claimed invention to one of ordinary skill in the art. See, e.g., *In Re Dow Chemical*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988), and *In re Keller*, 208 U.S.P.Q.2d 871, 881 (C.C.P.A. 1981).

The Applicant has canceled claims 4 and 7. Consequently, the rejection of claims 4 and 7 is rendered moot.

Applicant respectfully submits that claims 1 - 3, 5, 6, 8, and 11 - 14, as amended, are patentable for at least the reason that the cited reference fails to disclose, teach, or suggest each feature in the amended claims.

**1. Claims 1 - 3, 5, 6, 8, and 11 - 14**

Claim 1 is exemplary. For convenience of analysis, Applicant's independent claim 1, as amended, is repeated below in its entirety.

1. A connector sleeve, comprising:  
means for encompassing a portion of a tubing assembly junction having a first end proximal to a first end of the sleeve and a portion of a first tube proximal to the first end of the tubing assembly junction, the means for encompassing a portion of the tubing assembly junction that enables observation of the tubing assembly junction within the length of the sleeve while securing the first tube to the tubing assembly junction; and  
means for encompassing a portion of a second tube proximal to a second end of the tubing assembly junction, the means for encompassing a portion of the second tube enabling observation of the second tube within the length of the sleeve while securing the second tube to the tubing assembly junction, ***the connector sleeve configured to receive an assembled tubing assembly junction.***

(Applicants' amended independent claim 1 - *emphasis added*.)

The proposed combination of *Shoor* and *Desecki* fails to disclose, teach, or suggest at least the emphasized feature of pending claim 1 as shown above. Consequently, claim 1 is allowable.

Specifically, the proposed combination fails to disclose, teach, or suggest a connector sleeve configured to receive an assembled tubing assembly junction.

In this regard, the Detailed Action of the Office Action (page 2) concludes that *Shoor* fails to disclose an opening for observing the tubing junction. Applicant agrees. The Detailed Action further alleges that *Desecki* discloses a tubing junction with a slot in the casing that provides a slot for a locking mechanism. The Office Action further alleges that the slot may also allow one to observe the connection between the housing and the tubing.

The proposed combination of *Shoor* and *Desecki* cannot disclose, teach, or suggest Applicant's claimed connector sleeve for at least the reason that *Shoor* and *Desecki* fail to disclose, teach, or suggest a sleeve that can receive an assembled tubing assembly junction.

FIGs. 1A and 3 of *Shoor* apparently illustrate how a terminal connector (10) is arranged to engage a second terminal connector (11). FIGs. 1B, 1C, 2A, and 2B of *Shoor* apparently illustrate how internal features of terminal connectors (10) and (11) create a multiple-part resealable assembly that totally surrounds a first tube (18), a second tube (44), and a tubing junction (20a). FIG. 1B shows a first tube and a second tube separated from each other by membrane 31. FIG. 1C illustrates second tube (44) in fluid communication with first tube (18) after penetration of membrane 31 by the second tube (44). *Shoor* clearly illustrates the fluid communication of the first tube (18) and second tube (44) within an already coupled terminal connector assembly comprising terminal connector (10) and terminal connector (11) after a physical manipulation of the second tube (44) relative to the membrane (31). It is only after the physical manipulation that a tubing assembly junction is formed. Thus, *Shoor* does not disclose, teach, or suggest a connector sleeve that can receive an assembled tubing junction assembly.

Furthermore, each of the FIGs. 1A - 1C, 2A, 2B, and 3 illustrate *Shoor*'s resealable device using cross-sectional views to reveal interior structures of the device. Thus, each of the multiple parts forming the resealable device entirely surround / form the tubing junction (20a) and cannot permit external observation of a tubing assembly junction within a sleeve. Accordingly, *Shoor* does not disclose, teach, or suggest each feature of Applicant's claimed connector sleeve.

In accordance with the Abstract, *Desecki* apparently discloses a cannula and injection site coupling system comprising a cannula assembly having a blunt cannula or piercing member partially surrounded by a protective shield. The protective shield is spaced apart from the blunt cannula and includes a bayonet arm, a bayonet barb, a bayonet lock, and an opening or gap. When the cannula assembly and the injection site are coupled, the injection site arm is lodged within the cannula assembly lock opening. FIG. 6 of *Desecki* apparently illustrates an assembled tubing assembly junction. FIG. 7 of *Desecki* apparently illustrates how tubing (192) within a luer cap (196) is coupled to bayonet lock cannula (82) and how bayonet lock cannula (82) is further coupled to a Y-site. The Y-site is described as having a resealable septum carried by a first end of the Y-site (the end that engages the blunt cannula when the assembly is in fluid communication.) *Desecki* clearly illustrates the fluid communication of tubing (192) and Y-site (36) within bayonet lock cannula (82) after a physical manipulation of the luer cap (196) with respect to a first end of the bayonet lock cannula (82) and a physical manipulation of the bayonet lock cannula (82) with respect to the resealable septum within the Y-site (36). It is only after these physical manipulations that a tubing assembly junction is formed. Thus, absent from *Desecki* is a teaching or suggestion of a connector sleeve that can receive an assembled tubing junction assembly.

In contrast with the connector of *Shoor* and the slot in the casing (the bayonet cannula (82)) as apparently disclosed in *Desecki*, Applicant's claimed connector sleeve is configured to receive an assembled tubing assembly junction. For at least the reasons described above, the proposed combination of *Shoor* and *Desecki* fail to disclose, teach, or suggest Applicant's claimed connector sleeve.

Because independent claim 1 is allowable, dependent claims 2, 3, 5, 6, and 8 - 14, which depend either directly or indirectly from claim 1, are also allowable. *See In re Fine*, 837, F.2d 1071, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). Accordingly, Applicant respectfully requests that the rejection of claims 1 - 3, 5, 6, and 8 - 14 be withdrawn.

**C. Discussion of the Rejection - Claims 13 and 20 - 27**

In order for a claim to be properly rejected under 35 U.S.C. §103, the combined teachings of the prior art references must suggest all features of the claimed invention to one of ordinary skill in the art. See, e.g., *In Re Dow Chemical*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988), and *In re Keller*, 208 U.S.P.Q.2d 871, 881 (C.C.P.A. 1981).

Applicant respectfully submits that claims 13 and 20 - 27, as amended, are patentable for at least the reason that the cited reference fails to disclose, teach, or suggest each feature in the amended claims.

**1. Claim 13**

Claim 13, as amended, depends indirectly from independent claim 1 and includes all the features of intervening dependent claims 5, 6, and 9. Thus, claim 13 includes the feature that the connector sleeve is configured to receive an assembled tubing assembly junction. Claim 13 further includes the feature that “the means for encompassing a portion of the tubing assembly junction” enables observation of “the tubing assembly junction within the length of the sleeve while securing the first tube to the tubing assembly junction.” In addition, claim 13 further includes the feature that “the means for encompassing a portion of the second tube” enables observation of “the second tube within the length of the sleeve while securing the second tube to the tubing assembly junction” via “a tapered inner surface of the housing.” The proposed combination of *Shoor*, *Desecki*, and *Graves* fails to disclose, teach, or suggest the combination of these features. Accordingly, for at least this reason, dependent claim 13 is allowable.

In this regard, the Office Action alleges that *Graves* discloses a connector with a lockable safety assembly that includes a latch with a slot (72) that receives tubing (36). The Office Action concludes that it would have been obvious to one of ordinary skill in the art at the time of Applicant’s application to create a slot of an appropriate diameter to retain the tubing therein in order to prevent the connected sections from becoming disengaged.

Applicant submits that the proposed combination of *Shoor*, *Desecki*, and *Graves* fails to disclose, teach, or suggest Applicant’s claimed connector sleeve which recites the combination of a means for encompassing a portion of the tubing assembly junction that enables observation of the tubing assembly junction within the length of the sleeve while securing the first tube to the

tubing assembly junction; a means for encompassing a portion of the second tube that enables observation of the second tube within the length of the sleeve while securing the second tube to the tubing assembly junction comprising a tapered inner surface of the housing; and the feature that the connector sleeve is configured to receive an assembled tubing assembly junction. For at least this reason, Applicant's dependent claim 13, as amended, is allowable over the combination of *Shoor*, *Desecki*, and *Graves* and the rejection of claim 13 should be withdrawn.

## 2. Claims 20 - 27

Claim 20 is also exemplary. For convenience of analysis, Applicant's independent claim 20, as amended, is repeated below in its entirety.

20. A connector sleeve, comprising:  
***a housing configured to receive an assembled tubing assembly junction***, the housing comprising:  
***a first portion that includes an aperture along the longitudinal axis of the sleeve and a restrictor that intrudes from the housing***, the first portion configured to encompass a portion of a tubing assembly junction and contact a first end of the tubing assembly junction; and  
***a second portion that includes a slot along the longitudinal axis of the sleeve and a tapered inner surface, the second portion configured to closely surround and contact a second end of the tubing assembly junction along the tapered inner surface.***

(Applicants' amended independent claim 20 - *emphasis added*.)

The cited art of record fails to disclose, teach, or suggest at least the emphasized elements of pending claim 20 as shown above. Consequently, claim 20 is allowable.

As described above regarding the patentability of Applicant's claim 1, *Shoor* fails to disclose, teach, or suggest Applicant's claimed housing, first portion, and second portion. Specifically, *Shoor* clearly illustrates the fluid communication of the first tube (18) and second tube (44) within an already coupled terminal connector assembly comprising terminal connector (10) and terminal connector (11) after a physical manipulation of the second tube (44) relative to the membrane (31). It is only after the physical manipulation that a tubing assembly junction is formed. Thus, *Shoor* does not disclose, teach, or suggest a connector sleeve that can receive an assembled tubing junction assembly. Furthermore, *Shoor* does not disclose, teach, or

suggest a first portion that includes an aperture along the longitudinal axis. Moreover, *Shoor* does not disclose, teach, or suggest a second portion that includes a slot along the longitudinal axis of the sleeve.

*Desecki* clearly illustrates the fluid communication of tubing (192) and Y-site (36) within bayonet lock cannula (82) after a physical manipulation of the luer cap (196) with respect to a first end of the bayonet lock cannula (82) and a physical manipulation of the bayonet lock cannula (82) with respect to the resealable septum within the Y-site (36). It is only after these physical manipulations that a tubing assembly junction is formed. Thus, absent from *Desecki* is a teaching or suggestion of a connector sleeve that can receive an assembled tubing junction assembly.

Furthermore, *Desecki* does not disclose, teach, or suggest a first portion that includes an aperture along the longitudinal axis. Note that both the first and third portions of the multi-part assembly illustrated in FIGs. 6 and 7 of *Desecki* do not include apertures along the longitudinal axis. Thus, *Desecki*, which illustrates only a bayonet lock cannula having an aperture, cannot disclose, teach, or suggest Applicant's first and second portions, which both include apertures along the longitudinal axis of the sleeve. Accordingly, *Desecki* cannot be said to disclose, teach, or suggest features that when combined with *Shoor* would render Applicant's claimed connector sleeve obvious.

Moreover, the latch apparently disclosed in *Graves* does not remedy the failure of the combination of *Shoor* and *Desecki* to disclose, teach, or suggest all features of Applicant's claimed connector sleeve. *Graves* apparently discloses a lockable safety assembly for protecting a hyperdermic needle in an intravenous set. *Graves'* latch 62 does not permit observation of the second tube within the length of the sleeve (latch) while securing the second tube to the tubing assembly junction. *Graves'* lockable safety assembly pivots about the exterior of a housing at one end of the assembly. Accordingly, *Graves* does not disclose, teach, or suggest Applicant's claimed "second portion that includes a slot along the longitudinal axis of the sleeve and a tapered inner surface, the second portion configured to closely surround and contact a second end of the tubing assembly junction along the tapered inner surface." For at least the reason that the combination of *Shoor*, *Desecki*, and *Graves* entirely fails to disclose, teach, or suggest at least the claimed combination of features of Applicant's claimed connector sleeve, claim 20 is not rendered obvious and is allowable over the proposed combination.

Because independent claim 20 is allowable, dependent claims 21 - 27, which depend either directly or indirectly from claim 20, are also allowable. *See In re Fine, supra*. Accordingly, Applicant respectfully requests that the rejection of claims 20 - 27 be withdrawn.

### **III. Patentability of New Claims 28 - 30**

New claims 28 - 30 are patentable over the cited art of record for at least the reason that the references alone or in combination fail to disclose, teach, or suggest all features of independent claims 1 and 20, from which claims 28 - 30 depend. New claims 28 - 30 should be accepted because they raise no new issues of patentability with regard to *Shoor, Desecki*, and *Graves*.

### **IV. Prior Art Made of Record**

The prior art made of record has been considered, but is not believed to affect the patentability of the presently pending claims.

### **CONCLUSION**

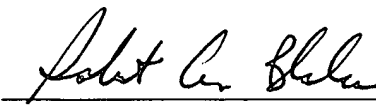
In summary, Applicant respectfully requests that all outstanding claim rejections be withdrawn. Applicant respectfully submits that all pending claims 1 - 3, 5, 6, 8 - 14, and 20 - 30 are allowable over the cited art and the present application is in condition for allowance. Accordingly, a Notice of Allowance is respectfully solicited. Should the Examiner have any comment regarding the Applicant's response or believe that a teleconference would expedite prosecution of the pending claims, Applicant requests that the Examiner telephone Applicant's undersigned attorney.

Respectfully submitted,

**THOMAS, KAYDEN, HORSTEMEYER  
& RISLEY, L.L.P.**

100 Galleria Parkway, Suite 1750  
Atlanta, Georgia 30339-5948  
(770) 933-9500

By:

  
Robert A. Blaha  
Registration No. 43,502